

REMARKS

The claims are 22-47 with claims 22, 38 and 39 being independent. Claims 1-21 have been cancelled without prejudice or disclaimer.

To expedite prosecution of the subject application, Applicants have presented new claims that are limited to the use of a specific insulin sensitizer, 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof, in a pharmaceutically acceptable form (or rosiglitazone), specifically the use of 2- 8 mg per day of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof, in a pharmaceutically acceptable form. Applicants specifically wish to note that they reserve the right to file continuation/division applications to present claims directed to the use of other insulin sensitizers described in the present application.

Support for claims 22-47 may be found throughout the subject specification. For example, support for claims 22-24 may be found in original claims 1-12 and in the specification at page 2, lines 5-12 and at page 3, lines 19-34. Support for claim 25 may be found in the specification at page 7, lines 5-12. Support for claim 26 may be found in the specification at page 6, lines 19-33. Support for claims 27-30 may be found in the specification at page 2, line 33 to page 3, line 3. Support for claims 31-36 may be found in the specification at page 4, lines 6-13. Support for claim 37 may be found in the specification at page 2, lines 10-13, page 6, line 19 to page 7, line 10. Support for claim 38 may be found in original claim 1 and in the specification at page 2, lines 5-13 and at page 6, line 4. Support for claim 39 may be found in original claims 14-18, in the specification at page 6, line 19 to page 7, line 10. Support for claim 40 may be found in original claim 3 and in the specification at page 3, lines 13-14. Support for claims 41-46 may be found in the specification at page 4, lines 6-13. Support for claim 47 may be found in the specification at page 9. No matter has been added.

For the avoidance of doubt, Applicants note that, as set forth in the specification, "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione" (or "Compound (I)") may exist in one of several tautomeric forms, as individual tautomeric forms or as mixtures thereof, all of which are encompassed by the terms "Compound (I)" or "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione". Furthermore, 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione contains a chiral atom, and therefore can exist in up to two stereoisomeric forms. The term "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione" (or "Compound (I)") also encompasses all of these isomeric forms, whether as individual isomers or as mixtures of isomers, including racemates. See the specification at page 4, lines 27-31. Accordingly, when reference is made to "Compound (I)", or to "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione", or to "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof", or to

"said 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione ", all tautomeric and isomeric forms of the compound are intended to be encompassed.

Additionally for the avoidance of doubt, as set forth in the specification, when reference is made to scalar amounts, including mg amounts and % weight amounts, of "5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof, in a pharmaceutically acceptable form", the scalar amount referred to is made in respect of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione per se: for example, 2 mg of Compound (I), or 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, in the form of the maleate salt is that amount of maleate salt which contains 2 mg of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (not: 2 mg of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleate salt). See the specification, page 5, line 37 to page 6, line 3.

Accordingly, the insulin sensitizer used in present invention, 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, can be administered in any pharmaceutically acceptable form (for example, as the free base or as a salt or as a solvate or as a solvate of a salt, etc.), however, the amount of sensitizer administered is based upon the weight of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione in the pharmaceutically acceptable form (e.g., the molecular weight of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleate is 473.52 g/m, whereas the molecular weight of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione is 357.44 g/m).

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Respectfully submitted,


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